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Dockets Management Branch (HFA-305)
Food and Drug Administration
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via e-mail: http://www.fda.gov/dockets/ecomments

RE: Comments on Proposed Notice of Rulemaking, Docket No. 02N-0276 and 02N-0278

Dear Sir or Madam:

The Northern Border Customs Brokers Association (NBCBA) supports the efforts of our Congress and the U.S. Food and Drug Administration to protect the food supply. As Americans, we are aware of the need for heightened security, illustrated by the events of September 11, 2001. We support the efforts of our government to protect the American public and understand the important role we as Customs brokers play in those efforts.

At the same time, as members of the international trade community, we believe we are uniquely situated to draw on our experience with regard to importation of food across our shared border with Canada. We understand the importance of international trade to the economic well being of the United States. We further understand and process commercial shipments of food entering the United States on a daily basis. We acknowledge FDA's proposed regulations would have a dramatic effect on the way all parties in the supply chain conduct business.

We therefore respectfully submit the following comments to the proposed rule for Registration of Facilities:

Registration of Facilities:

For both domestic and foreign facilities, the FDA is proposing that the owner, operator or agent in charge register the facility. The FDA also recommends that if a foreign facility wants to designate it's U.S agent as its agent in charge for purposes of registering, that the facility and the U.S agent

enter into a written agreement authorizing the U.S agent to register the facility and specifying the U.S. agent's other responsibilities.

We believe further clarification is needed from the FDA on the term "agent in charge" for registration purposes and the responsibilities and liabilities of this party.

With regards to what facilities must register, we feel that it is not economical nor efficient to require such facilities that are providing temporary storage for food products for reasons of normal transportation activities such as cross docking, or for temporary holding waiting for Customs, FDA or other government agency release as in the case of a CFS.

Because a single domestic U.S. transportation company – even one of small or moderate size may have literally dozens or hundreds of such locations, the separate registration of each of them as an individual facility (through which imported food products might occasionally pass) will be a huge and unreasonable burden upon many such firms.

We offer the following comments on the proposed rules for Prior Notice:

Non-Resident Importers of Record Should be Authorized to Submit Prior Notice

FDA proposes to limit those parties authorized to submit prior notice to purchasers or importers who reside or maintain a place of business in the United States, or an agent of one of those parties acting on their behalf.

To limit the party responsible for providing prior notice to U.S. entities completely ignores the fact that for the majority of food product shipments from Canada, the foreign exporter is the Non-Resident Importer of Record (NRI) and the broker is acting as their agent. The U.S. importer is not the client of the broker, rather these shipments arrive at the border with title and ownership remaining with the seller because (1) the terms of sale are on a delivered vs. port of origin basis, or (2) the goods have not been sold and are on a consignment shipped typically to a warehouse for storage. Under these circumstances, we contend that the most appropriate party to provide the prior notice would be the non-resident importer or their designated agent.

The negative impact of proposed § 1.285 on the importing community in the United States, as well as in other countries, but primarily Canada, cannot be overstated. FDA must allow NRIs to submit prior notice or to designate an agent for this purpose.

Agents

Please explain what liability attaches to a Customs broker who acts as U.S. agent for purposes of prior notification to FDA.

Customs brokers are in a natural position to serve as a U.S. Agent. Customs regulations require the existence of a power of attorney to transact customs business executed by a nonresident principal who also has authorized the broker to accept service of process on his behalf. Customs brokers would be more inclined to act as the *U.S. Agent* if their responsibilities and liabilities proposed by FDA were no more onerous than acting as a communications link. FDA should adopt a position similar to that of Customs, that the broker should not be held responsible for the accuracy of the advanced information provided to them from their customer.

Prior Notice Information and ACS Data

FDA's proposed level of specificity is not mandated by Congress.

Section 307 of the Act requires that the notice provide the identity of each of the following: The article, the manufacturer and shipper of the article, the grower of the article if known within the specified time period the notice is required to be provided, the country from which the article originates, the country from which the article is shipped, and the anticipated port of entry for the article.

Additionally, FDA states in the Proposed Notice of Rule Making (NPRM) that the information in the prior notice will not be used to make admissibility decisions.

Except for the grower of the article, (which is conditional) entries made through the ABI/ACS/OASIS system include all of the information required by the statute.

Further, FDA admits in the NPRM, "We currently receive the majority of information we base admissibility decisions on electronically from US Customs. Thus, we already have the electronic capability to process and screen the information."

If OASIS information is capable of providing the information for "admissibility" determinations then the information logically should meet the pre-arrival requirements.

Automation - Prior Notice via ACS/OASIS vs. the Internet

FDA is proposing that the prior notice, amendments and updates be submitted electronically to FDA though FDA's new web based Prior Notice System.

Use of a web-based system is not conducive to the high volume of transactions generated by many of the largest brokers and importers. When combined with the current use of ABI/ACS and OASIS, the FDA's web-based Prior Notice System becomes not only inefficient, but also redundant.

Additionally, because prior notice information would be submitted via a system separate from that upon which the U.S. Customs entry and FDA OASIS information is filed, and possibly by different parties, the potential exists that a high percentage of prior notices will not match corresponding entries and FDA OASIS submissions. This duplicative reporting will lead to even greater costs to the importing community and consumers of imported food, will compromise the integrity of data supplied to FDA, foster confusion, deter compliance and congest ports.

We strongly believe the requirement to submit prior notice via the Internet is inconsistent with the ITDS initiatives that the Trade, FDA and other participating government agencies are championing today.

Further support and evidence of this trend of a single interface can be obtained from the United Nations Economic Commission for Europe document titled, "The Single Window Concept".

ACS Timing Modifications Required to Support Advance Notice

Currently, ABI entry filers have the ability through the ACS system to transmit FDA information in advance of the shipments arrival. It is our understanding that when a release is requested utilizing the CF7501 certified information, Customs ACS system sends the FDA information to OASIS at the same time. Therefore, if this data is given to Customs in advance of the arrival of the shipment, FDA has this information as well. However, for shipments released using Cargo Selectivity or Border Cargo Selectivity, this information is not transmitted to FDA's OASIS system until the shipment is at the port and is "arrived" in the ACS system by the Customs inspector. For this information to be available to FDA prior to arrival, data would have to be sent to OASIS when the Cargo Selectivity or Border Cargo Selectivity records are received in ACS. This minor modification to provide advance information should be a simple change.

Reporting Time Frame

FDA's proposed requirement that prior notice be submitted by noon the day prior to arrival is inconsistent with the legislative mandate of "maintaining flexibility when setting the minimum time required for prior notice and taking into account different modes of transportation, the nature of perishable food, and the needs of businesses which operate close to the U.S. border." Some of the United States and Canada's largest cities are located in close proximity to the border. Their economies rely heavily on businesses who utilize "just in time" inventories or short-notice shipments destined from Canada to the United States.

We believe the proposed reporting time frame is unrealistic and will have a negative impact on trade with Canada and Mexico.

FDA Availability

In order to adequately protect the food supply while minimizing the disruption to international trade, we believe it is imperative that FDA increase its hours of operation, availability and staffing at US border ports. Importations occur on a 24-hours a day, 7 days a week basis at all major U.S. ports on the U.S/Canada border. International commerce depends on flexibility of import times and availability of officials at the border to examine and release imported shipments at all hours and on weekends. FDA's proposed regulations regarding prior notice will require the Agency's availability on a permanently expanded basis in order to properly administer its mandate from Congress.

Failure to Report Prior Notification

In proposed § 1.278(d), FDA places responsibility for arranging movement of noncompliant food shipments on "the person submitting the prior notice or the carrier." It is our contention that this responsibility belongs with the owner of the merchandise at the time of importation.

Shipments Not Released by FDA

In light of current security considerations, and in the interest of the American public, we recommend that the conditional release (FDA Review) be eliminated and only the "May Proceed" or "Hold" response be issued.

Secure Location Holds

In proposing to require that refused items be held at the port of arrival or directed to a secured facility, usually a Customs bonded warehouse, FDA indicates that "U.S. Customs has identified a well-established network of storage facilities that are secure." We disagree with this statement.

On the U.S /Canada border, especially at the remote East and West ports, there are very few facilities of this sort, that are available on a 24/7 basis with temperature controlled environments for perishables.

Amendments to Prior Notice

FDA proposes to require a party submitting prior notice to report the anticipated time when the food will arrive at the U.S. border. If the time of arrival is expected to be more than one hour earlier or more than three hours later than the anticipated time of arrival, FDA is proposing to require the submitter to update this information not less than two hours prior to arrival.

Although we are mindful of the FDA's need to be able to plan inspections, the "anticipated time of arrival" requirement, which is not required by the legislation, places unreasonable and unrealistic expectations on the party submitting prior notice to estimate when they believe the goods will arrive at the port of arrival. Parties are frequently unaware when their merchandise will arrive at the border. Shipments are regularly delayed more than three hours by border lineups and/or difficulties with documentation. Road construction, traffic congestion and other concerns are variables that commonly make transportation a difficult area in which to accurately estimate border arrival times.

The proposed regulations addressing updates to time of arrival do not adequately address the foregoing concerns. Further, this requirement for accurate time of arrival reporting introduces an additional party, the carrier, to the arrival communication process.

We recommend that FDA align with Customs to develop a mutually acceptable advanced arrival time frame by mode of transportation. We also recommend that for shipments from contiguous countries, FDA abandon the concept of an arrival update to the prior notice.

Transportation Entries

The proposed requirement to provide prior notice at the first U.S. port where merchandise will be placed for transportation in bond is an unnecessary burden to importers, carriers and brokers. The requirement will complicate the prior notice process and compromise the interest of efficient enforcement of the Federal Food, Drug and Cosmetic Act. Carriers rarely have access to all of the information required under proposed § 1.288, which would lead to more frequent submission of incorrect information. The number of additional prior notices that will have to be filed for merchandise simply transiting through the United States if subject to the prior notice requirement will place an unwarranted strain on already limited FDA resources, limiting the agency's ability to focus efforts on food imported into the United States.

The Bioterrorism Act does not require FDA to obtain prior notice of food presented at a port for transportation in bond.

We do not believe any benefit accrues to U.S. food safety by subjecting this type of shipment to prior notice requirements.

Risk Management/Security

CTPAT & FAST are recent Customs initiatives to assist in securing the supply chain for shipments crossing our borders. Companies are investing millions of dollars into securing their supply chains, voluntarily. Shipments from participating importers will be designated to be low risk and will be entitled to expedited release processing at the border. A FDA component of these initiatives should be considered in these proposed rules and participants of this verifiable supply chain security program should be granted consideration for waiver of the prior notice requirement.

Definitions

FDA needs to rethink any proposed changes to definitions of terms that are commonly used by the trade and other government agencies today. To require multiple definitions for basically the same term will cause confusion, resulting in inaccurate data being transmitted to different agencies.

Our comments on proposed definitions that are already in use today are:

Country from which the article of food was shipped: We believe that the country from which the article of food was shipped should be the country from which the goods were "exported" to the United States and should be the same as in the U.S. Customs regulations defining *country of export.* This information is reported on the Customs entry. There is no reason to require two definitions for what is essentially the same data element.

Originating country: We believe that the definition of this item be, substantively, the same as the "country of origin" definition under the U.S. Customs regulations.

Port of entry: We would suggest standardizing definitions with U.S. Customs and calling this the "port of arrival." , which is a commonly used term in the industry.

Conclusion: One System, One Timeframe

We recommend that FDA consider the following:

- Until ACE is available, accept the data currently provided (with minimal additions such as the registration number) through ACS/OASIS.
- Work with Customs to determine a common time frame for providing advanced information.
- Work with Customs to change the timing of the transmission of FDA information from ACS to OASIS, allowing this data to satisfy the prior notice mandate.

The NBCBA would like to work closely with FDA to develop and implement a solution that would satisfy the mandate FDA has been given to protect the safety and security of the United States food supply. Concurrently, we would like to ensure that the actions taken by the FDA have a minimal adverse impact on the trading community and the economy of our country.

Yours truly,

Leman G. Bown, Jr.
President

Deborah A. Benish
Chair – FDA Committee